

## **DETAILED ACTION**

### ***Status of claims***

Claims 1-25 have been canceled and new claims 26-33 have been added.

Claims 26-33 are under examination in the instant office action.

### **Rejections withdrawn**

Applicant's amendments and arguments filed on 05/10/2011 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn. Applicant's amendments have overcome the 112<sup>nd</sup> paragraph rejection of claim 21, 112 1<sup>st</sup> paragraph rejection of claims 20-22 , 102(b) rejection of claims 19-25 over Sair et al. (US 4,230,687) as evidenced by Wheat Flour (<http://en.wikipedia.org/wiki/Flour>) from the previous Office Action. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

### **New ground of rejections necessitated by Applicant's amendment**

The new claims 26-33 necessitate the following new ground of rejections.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1613

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claims 26-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Sair et al. (US 4,230,687) as evidenced by Wheat Flour (<http://en.wikipedia.org/wiki/Flour>).***

Sair et al. meet all of the limitations of claims 26-30, 32, and 33. Sair et al. disclose an encapsulation material forming protective matrix to encase vitamins (lipids) in order to prevent minimizing oxidation and controlling release of vitamins (lipids) comprising mixture of casein as a protein and Capsul as a pre-processed resistant starch (claim 1 and column 2, line 1 through column 9, line 24-28). Capsul is defined by Sair et al. as dextrin (example 25) and is disclosed as starch with increased number of sugar reducing groups in the instant specification (the paragraph bridges page 4 and 5, last paragraph on page 7, and example 3). Casein is defined as milk protein according to the disclosure in the instant specification (abstract). Sair et al. are silent about the active agents being storage unstable; however, Sair et al. disclose the active agents undergoing oxidation and flavor deterioration on storage which are understood as storage unstable. Sair et al. are silent about the encapsulation material releasing the therapeutic and nutritional agents in predetermined location in the gastro-intestinal tract. The encapsulation material disclosed by Sair et al. comprises the same components as the encapsulation material recited in the instant claim, thus the encapsulation material disclosed by Sair et al. would necessarily possess the same release property as that of the encapsulation material recited in the instant claim. Although the method disclosed by Sair et al. is not exactly the same as the claimed the method, the method recited in

Art Unit: 1613

claim 26, 27, 32, 33 is a product-by-process limitation. The determination of patentability of a product-by-process claim is based on the product itself, not its method of production. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. Both of the encapsulation material disclosed by Sair et al. and the claimed encapsulation material comprise the same components with the components being physically mixed, thus the product disclosed by Sair et al. would necessarily be the same as the claimed product. The burden is shifted to the applicant to provide evidence to demonstrate that the structure of the claimed encapsulation material resulted from the said process is different from that of the encapsulation material disclosed in the prior art. See MPEP 2113 [R-1].

Sair et al. meets all of the limitations of claim 31. Sair et al. discloses the starch being wheat flour (column 17, line 20-38). According to Wheat Flour wheat flour contains high proportion of starches (under Flour make up).

### Response to Arguments

Applicant's arguments, filed on 05/10/2011, have been fully considered but they are moot in view of new ground of rejections. However the examiner would like to address the following arguments.

Applicants argue that the material being produced by a process recited in claim 26 to ensure the mixture is homogenized to obtain an emulsion followed by spray-drying

Art Unit: 1613

while Sair reference discloses a process of encapsulating active agent with small amount of water content, thus no emulsion is formed and no homogenizing is involved in the process disclosed by Sair et al. thereby teaches away from the claimed material. Furthermore, Sair et al. do not disclose a spray-drying step in the process of producing the encapsulating material.

However, this argument is not deemed persuasive. First of all, as stated in the previous and instant office action, the method of producing the claimed material is a product-by-process limitation. If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. Secondly, Sair specifically state that the encapsulating material is mechanically homogenized into a thick paste which is air dried followed by grinding (example 25). Although the process disclosed by Sair et al. does not form emulsion with a large amount of water and does not have the spray-drying step as the process for preparing the claimed material, again, this is a product-by-process limitation and the burden is on the applicants to provide evidence to demonstrate that the structure of the claimed encapsulation material resulted from the said process is different from that of the encapsulation material disclosed by Sair et al. Thirdly, the amount of water in the process for preparing the claimed material is not claimed and is not in the final product, thus, is irrelevant. Lastly, this is a 102 rejection, not a 103 rejection. It is the Examiner's position that the reference fairly discloses all the limitations as discussed in detail above.

Respectfully, applicants' arguments are not persuasive. Accordingly, the claims remain rejected for at least these reasons and the reasons of record.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian-Yong Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1613

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/H. Y./

Examiner, Art Unit 1613

/Ernst V Arnold/

Primary Examiner, Art Unit 1613